

Clinical Agent Repository Inventory Management  
Computer Database System

**CARIM 2.2**



**System Description**

NIAID/DMID Office

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## **Introduction**

CARIM is an inventory management computer database system developed to effectively manage and control all investigational drugs at the **Division of Microbiology and Infectious Diseases Clinical Agents Repository** (DMID-CAR).

The Clinical Agents Repository Inventory Management (CARIM) system has been designed and developed by Fisher Bioservices and Cascades Technologies Incorporated (CTI). CARIM is intended to manage all investigational drugs at the Division of Microbiology and Infectious Diseases Clinical Agents Repository (DMID-CAR).

There are three components that must be considered by users who want to access the WWW: hardware, software, and network connectivity. All three must be present and established in order to access the web effectively. CARIM is based upon World Wide Web (WWW) technologies. As such, it consists of a single database accessed by users across the Internet using a web browser, such as Netscape's Navigator or Microsoft's Internet Explorer. This approach provides the advantages of a centrally supported system as well as increased accessibility through the Internet. Using a web browser, users access the CARIM server and log into the application. After completing the login process, the user is presented with welcoming information and a menu of available options. Information related to CARIM data can then be entered, retrieved, or modified by the user just as if the data were located on his or her personal computer.

## **Project Description**

### **Background**

The CARIM computer database system has been designed to automate the receiving, shipping, inventory control, and activity report processes of the DMID Clinical Agents Repository (DMID-CAR).

### **Solution**

CARIM has been developed with Internet usability in mind. The Web server software for this project is Microsoft's Internet Information Services 6.0 (IIS). The ColdFusion Enterprise MX application server is used as the application server to connect the Web application to the database and provide dynamic content for the browser based CARIM application. All this architecture is based on the Microsoft's Windows 2003 server software. Fisher BioServices Inc, is providing the necessary server hardware and software licenses required for the project and it is targeted for users with version 5.0 or above of the Microsoft's Internet Explorer or Netscape Navigator browsers. The screens have been developed for a minimum screen resolution of 800 x 600 pixels. This will ensure that users with a wide array of monitor sizes and resolutions can see the system screens without scrolling sideways. The database has been developed following best practices for relational database design, data normalization, and development. This database is deployed on the Microsoft's SQL Server 2000 database server.



## System Overview

The DMID-CAR utilizes the CARIM application as the tool for receipt, processing, tracking and fulfillment of the products orders used in clinical trials. This section provides a brief overview of system features and functionality available in the CARIM application. Topics covered in this section include application functional overview, application security, navigation, and components.

### Functionality

- Receiving clinical agents from manufacturers and clinical sites
- Shipping clinical agents to manufacturers and clinical sites
- Adjustments and transfers of internal inventory
- System reports
- System administration

### Security

- 3 permission levels
- Log in protection
- Sessions are tracked

### Navigation

- Main / application menu on top
- Page / module menu on left side

### Components

Pages have specific components visible by the type of page. Most components are application wide and usually visible on all pages. Reports have specific components only available to reports. Forms have specific components only available to forms.

### Common

- Page Title
- Introduction
- Report or form
- Header
- Footer
- Main menu
- Page menu

**Reports**

- CARIM reports all contain page titles, report search boxes, tabular data, edit and delete controls, legend, pagination, user messaging, and an add record link

**Forms**

- CARIM forms all contain page title, form controls to add or edit data, user messaging , and confirmation pages

**Naming Conventions**

- Receipts (YYR-MMDDXX or YYRS-MMDDXX)
- Shipments (YYs-MMDDXX)
- HSROAD Orders (YYO-MMDDXX)
- Adjustments (YYA-MMDDXX)
- Transfers (YYT-MMDDXX)

The system features and its related functionality make this application an effective solution for automating the managing the Repository transaction process and creates a bridge for supporting the ordering products via the Order It Module in HSROAD. The following sections will provide a description of the functional processes of the application.

## Functional Process Description

The CARIM System is used by the DMID - CAR to conduct all repository transactions. These transactions include the receipt and shipment of investigational agents which are to be used in Clinical trials. The following sections will provide an overview of the features and functionality available within each module of the application which automates these processes.

### Login

When the user accesses CARIM from a web browser, they are presented with a log in screen. If an account has been pre-established, the user will use that User ID and password to gain access to the system. If no account has been provided, a user will not be able to access the application.

There is access privileges associated with the application. The application only displays the modules which the user has access to. If a particular module is inaccessible to the user, it won't be displayed. The modules that accessible to each user have been predefined by the system administrator and are linked to the user's account.

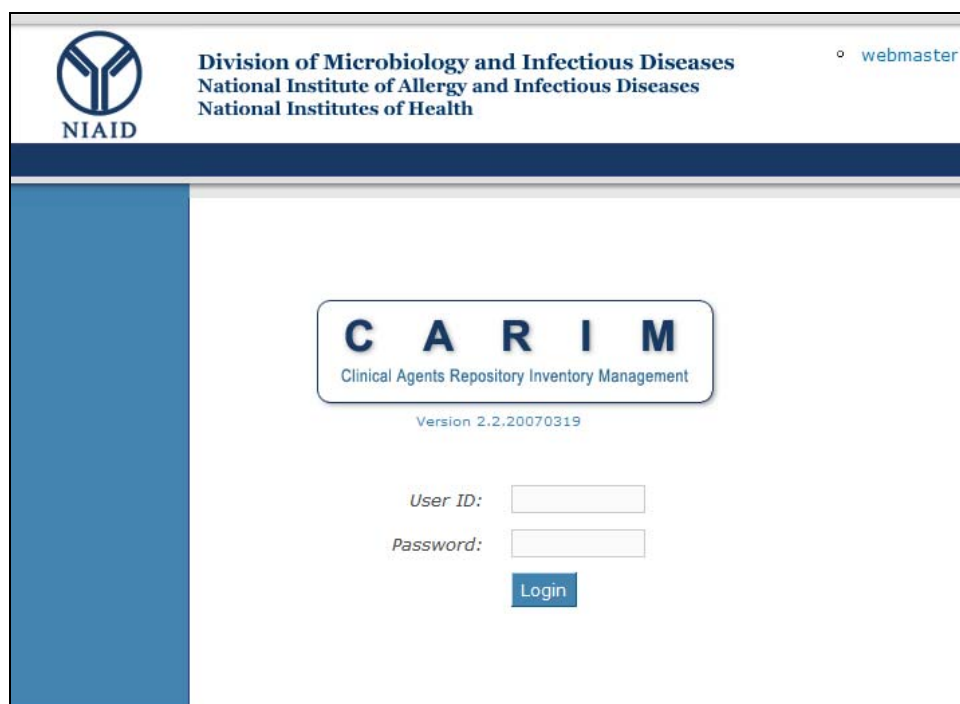
The screenshot shows the CARIM login interface. At the top left is the NIAID logo. To its right is the text: "Division of Microbiology and Infectious Diseases", "National Institute of Allergy and Infectious Diseases", and "National Institutes of Health". In the top right corner, there is a link labeled "webmaster". The main content area features the "CARIM" logo in large letters, with "Clinical Agents Repository Inventory Management" underneath. Below the logo, the version "Version 2.2.20070319" is displayed. The login section includes a "User ID:" label followed by a text input field, a "Password:" label followed by a text input field, and a blue "Login" button positioned below the password field.

Figure 1 CARIM Login Page

### Receiving Module

The Receiving Module is used to create, modify or delete all information pertaining to all received drug shipments. It is the process used to log products received by the Clinical Agent Repository into the CARIM system. The receiving module consists of two sub-modules and a dashboard.

Adding receipt records to CARIM follows a two step workflow. First, a new receipt is created by the receiving inspector. The receiving inspector is the user who first creates the receipt record in the system. The same or a different user, also defined as a receipt inspector may edit the record as often as required. Once created (and perhaps edited), another different user is required to confirm the receipt. Once confirmed the normal balance of inventory is affected, and the record is read-only in the system.

### Receiving Module Dashboard

The receiving module dashboard gives the user a single page view of all activity pending in the receiving module. From here all normal and return receipts are visible. Also, the user has links to view all receipts by type (normal or return) or to add a new receipt by type (normal or return).



Figure 2 Receiving Module Dashboard

### Receiving Normal Inventory of Clinical Agents

This area is designed to view, create, modify, or delete normal drug receipts. Typically, normal drug receipts are defined as products received from the manufacturer and shipped to the Clinical Agent Repository, then entered into the CARIM application. A transaction within this sub-module will affect the Normal, Rejected and Quarantined inventories. Once receipts are confirmed, the inventory of that product increases.

These types of receipts are designated in the system by a series of numbers and a letter “R” to identify it as a receipt. A typical drug receipt number may be 02R-021201. These numbers equate to transactions within the inventory module. See the Naming Convention section for more information.

## Normal Receiving Report

The normal drug receipt information report displays a list of all clinical agents received in CARIM in the past 3 years adding to the normal inventory balance. Completed transactions will have a confirm date visible; uncompleted transactions will not. From this report the user may add a new drug to the normal inventory, or edit or delete an existing but yet to be completed transaction. Completed transactions are read only. Users may also search all receipt transactions using the search box or the record set pagination controls.

Data displayed in this report includes the Receipt Number, Product number, Product Name (ID - lot number – label name), the receipt inspector name, the receipt confirmation name, and the date the record was confirmed. An action column is displayed providing icons to edit or delete unconfirmed normal receipt records.

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Receiving | Shipping | Inventory | Reports | System Administration

**Normal Drug Receipt Information**

Select a receipt number below or enter a receipt number in the search to view or modify a normal drug receipt record. To add a new normal drug receipt, simply click the *Add normal drug receipt* link to the right.

Search normal receipts:  search

Search criteria: All normal drug receipts

[Add normal drug receipt](#)

Edit X Delete Page: 1 2 3 4 5 6 7 8 9 10 > >> 1 - 20 of 333 records


Action	Receipt Number	Product (ID - Lot - Label)	Inspected By	Confirm Date	Confirmed By
	07R-040302	07R-040302-07R-040302-07R-040302	07R-040302	04/03/2007	07R-040302
	07R-040301	07R-040301-07R-040301-07R-040301	07R-040301	04/03/2007	07R-040301
	07R-033001	07R-033001-07R-033001-07R-033001	07R-033001	03/30/2007	07R-033001
	07R-030901	07R-030901-07R-030901-07R-030901	07R-030901	03/09/2007	07R-030901
	07R-030101	07R-030101-07R-030101-07R-030101	07R-030101	03/01/2007	07R-030101

**Figure 3 Normal Receiving Report**

## Normal Receiving Form

The appropriate form to add, edit or delete a normal receipt is accessible by clicking the *Add normal drug receipt* link, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional defined for normal drug receipts. Required fields are denoted by the red line to the right of the form field label.



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Normal  
Returns

### Add Normal Drug Receipt

Receipt Number

Carrier

Supplier's Ship Number

Product

Manufacturer

Expiration Date  format: mm/dd/yyyy

Volume/Weight  /

Unit Type

Units Per Container

**Units**

Please enter the number of units for each type of inventory.

Normal Received

Quarantine Received

Rejected Received

Environment

Storage Temperature

	Yes	No	Comments
Inspected	<input checked="" type="radio"/>	<input type="radio"/>	<input type="text" value="(1)"/>
COA Enclosed	<input type="radio"/>	<input checked="" type="radio"/>	<input type="text" value="(2)"/>
Label Meets Minimum GMP Requirements	<input type="radio"/>	<input checked="" type="radio"/>	<input type="text" value="(3)"/>
Label Copy Filed	<input type="radio"/>	<input checked="" type="radio"/>	<input type="text" value="(4)"/>
Temperature Monitor Enclosed	<input type="radio"/>	<input checked="" type="radio"/>	<input type="text" value="(5)"/>
Retention Sample Required	<input type="radio"/>	<input checked="" type="radio"/>	<input type="text" value="(6)"/>

DMID Protocol Number

Protocol Short Name

Protocol IND Number

IND Title

Comments

Inspected By

Note: required fields

Figure 4 Normal Receiving Form

## Return Drug Receipts

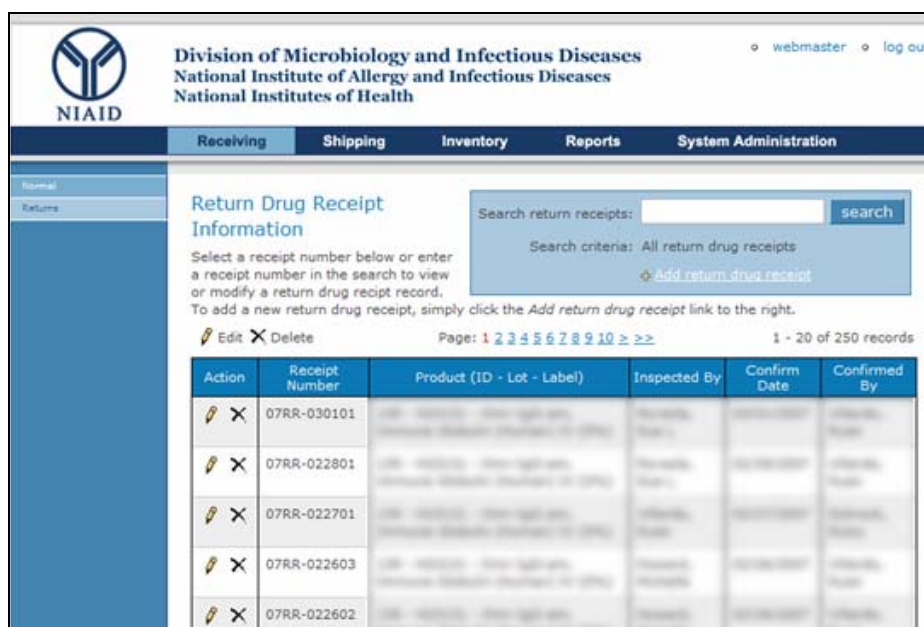
This area is designed to view, create, modify, or delete return drug receipts. Typically, return drug receipts were previously shipped to Protocol Investigators at the clinical site and then returned to the Clinical Agent Repository. A transaction within this sub-module will affect the return used and return unused inventories. Once receipts are confirmed, the inventory of that product increases.

These types of receipts are identified in the system by a series of numbers and the letters “RR” to identify it as a return receipt. A typical return drug receipt number may be 02RR-031801. These associate to transactions within the inventory module. A transaction within this sub-module will affect the Return Unused and Return Used repositories.

## Return Drug Report

The return drug receipt information report displays a list of all clinical agents returned to the repository and logged CARIM in the past 3 years. Completed return transactions will have a confirm date visible; uncompleted transactions will not. From this report the user may add a new drug to the return used or unused inventories, or edit or delete an existing but yet to be completed transaction. Completed transactions are read only. Users may also search all receipt transactions using the search box or the record set pagination controls.

Data displayed in this report includes the Receipt Number, Product Name (ID - lot number – label name), the receipt inspector name, the receipt confirmation name, and the date the record was confirmed. An action column is displayed providing icons to edit or delete unconfirmed return receipt records.



Action	Receipt Number	Product (ID - Lot - Label)	Inspected By	Confirm Date	Confirmed By
	07RR-030101	07-000000-000000-000000	07-000000	07-000000	07-000000
	07RR-022801	07-000000-000000-000000	07-000000	07-000000	07-000000
	07RR-022701	07-000000-000000-000000	07-000000	07-000000	07-000000
	07RR-022603	07-000000-000000-000000	07-000000	07-000000	07-000000
	07RR-022602	07-000000-000000-000000	07-000000	07-000000	07-000000

**Figure 5 Return Drug Report**

## Return Drug Form

The appropriate form to add, edit or delete a return receipt is accessible by clicking the *Add return drug receipt* link, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional defined for adding return drug receipts into CARIM. Required fields are denoted by the red line to the right of the form field label.

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Receiving Shipping Inventory Reports System Administration

Normal  
Returns

### Add Return Drug Receipt

Receipt Number

Protocol Type ☒ DMID ☐ Non-DMID

**Protocol Information**

DMID Protocol Number

Protocol Short Name

Protocol IND Number

IND Title

Performance Site

Protocol PI

Carrier

Supplier's Ship Number

Product

Manufacturer

Expiration Date  format: mm/dd/yyyy

Volume/Weight  /

Unit Type

Units Per Container

Units Used Received

Units Unused Received

Reason For Return

Environment

Storage Temperature

Received Return Agent Form ☐ Yes ☒ No

Comments

Inspected By

Add Return Drug Receipt cancel

Note: required fields

Figure 6 Return Drug Form



## Shipping Module

The Shipping Module is used to create, modify or delete all information pertaining to all product shipments. It is the process used to log the shipped products into the CARIM system.

### Shipping Module Dashboard

The shipping module dashboard gives the user a single page view of all pending activity in the shipping module. From here all DMID IND for human use, Non-DMID for human use, DMID not for human use, return shipments, and HSROAD orders are visible. Also, the user has links to view all shipments by type or to add a new receipt by type.

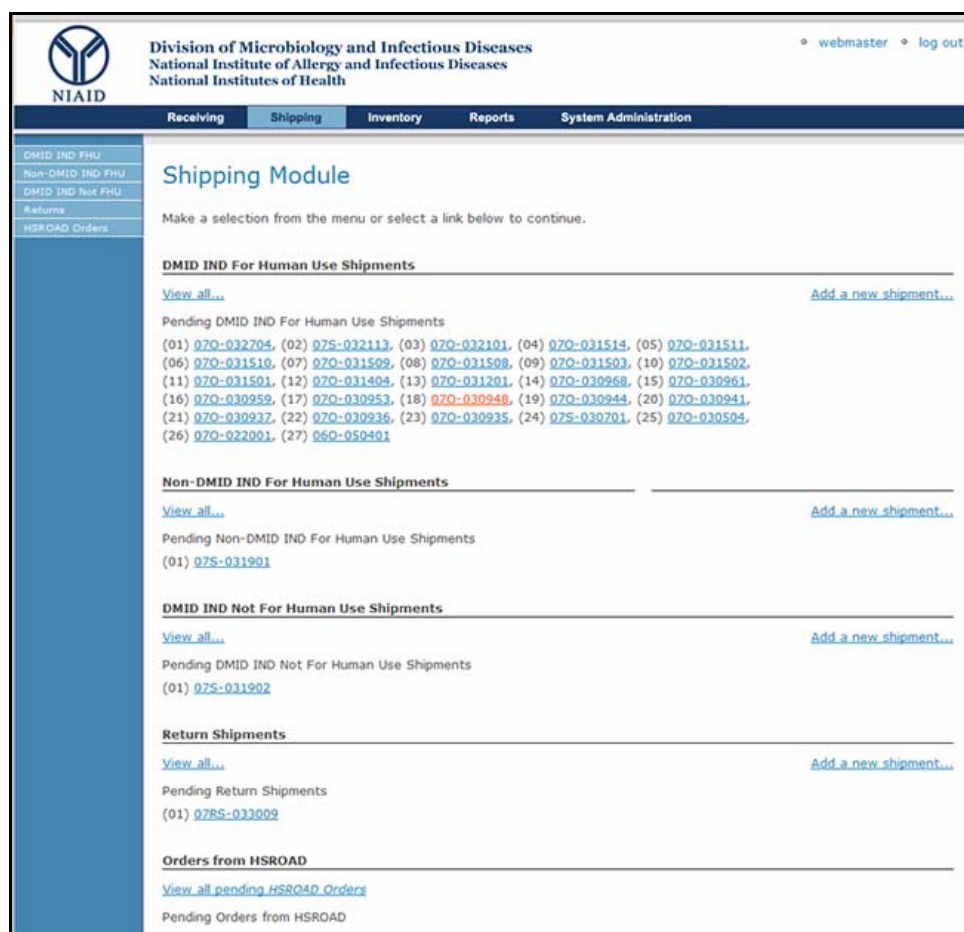


Figure 7 Shipping Module Dashboard

### DMID IND For Human Use Shipments

This area is designed to create, modify, or delete a shipment of DMID IND clinical agents intended for human use. These types of shipments are identified in the system by a series of numbers and the letter "S" to identify it as a shipment, a typical drug shipment number may be 02S-031801. For more information refer to the previous section - Naming Conventions. These in turn become transactions within the inventory module affecting only the Normal repository.

## DMID IND For Human Use Shipment Report

The DMID IND for Human Use Shipment report displays a list of all For Human Use shipments made from the Repository to clinical sites in the past 3 years subtracting from the normal inventory balance. Completed transactions will have a confirm name visible; uncompleted transactions will not. From this report the user may add a new shipment, edit or delete an existing but yet to be completed transaction. Completed transactions are read only. Users may also search all receipt transactions using the search box or the record set pagination controls.

Data displayed in this report includes the Shipping Number, Shipping Date, the Shipping inspector name, the Shipping confirmation name, and the name of recipient Clinical Site. An action column is displayed providing icons to edit or delete unconfirmed DMID IND For Human Use records.

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Receiving Shipping Inventory Reports System Administration

DMID IND FHU  
Non-DMID IND FHU  
DMID IND Not FHU  
Returns  
HSR/ORD Orders

### DMID IND For Human Use Shipments

Select a Shipping Number below or enter a Shipping Number in the search to view or modify a human use drug receipt record. To add a new shipment, simply click the [Add a DMID IND For Human Use Shipment](#) link to the right.

Search DMID IND For Human Use shipments:

Search criteria: All DMID IND For Human Use shipments  
[Add a DMID IND For Human Use Shipment](#)

1 - 20 of 476 records


Action	Shipping Number	Shipping Date	Inspected Name	Confirmed Name	Site
	070-040301	04/03/2007	Thomas, Mary	Thomas, Mary	University of Maryland Medical Center
	070-040201	04/02/2007	Thomas, Mary	Thomas, Mary	University of Maryland Medical Center
	070-032202	03/22/2007	Thomas, Mary	Thomas, Mary	University of Maryland Medical Center
	070-032201	03/22/2007	Thomas, Mary	Thomas, Mary	University of Maryland Medical Center
	070-031502	03/15/2007	Thomas, Mary	Thomas, Mary	University of Maryland Medical Center
	070-031501	03/15/2007	Thomas, Mary	Thomas, Mary	University of Maryland Medical Center

Figure 8 DMID IND For Human Use Shipment Report

## DMID IND For Human Use Shipment Form

The appropriate form to add, edit or delete a shipment of this type is accessible by clicking the *Add a DMID IND for Human Use Shipment* link, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for DMID IND For Human Use shipments. Required fields are denoted by the red line to the right of the form field label.



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[DMID IND FHU](#)  
[Non-DMID IND FHU](#)  
[DMID IND Not FHU](#)  
[Returns](#)  
[HSROAD Orders](#)

## Add DMID IND For Human Use Shipment

Shipment Number

Exemption To Ship ☐ Yes ☒ No

Exemption Date  format: mm/dd/yyyy

Carrier

DMID Protocol Number

Protocol Short Name

Protocol IND Number

IND Title

Performance Site

Protocol PI

IRB Approval

Protocol Not On Hold

30 Days Wait Satisfied

Form FDA 1572

PI Curriculum Vitae

AWB Number

Ordered By

Environment

Storage Temperature

Attention To

Site Department

Shipping Address 1

Shipping Address 2

Shipping Address 3

City

State/Province

Zip Or Postal Code

Country

Action	Item	Available	Units	Product	Manufacturer	Volume/Unit	Expiration
	1		<input type="text"/>	<input type="text" value="&lt;undefined&gt;"/>		/	

Comments

Inspected By

Note: required fields

Figure 9 DMID For Human Use Shipment Form

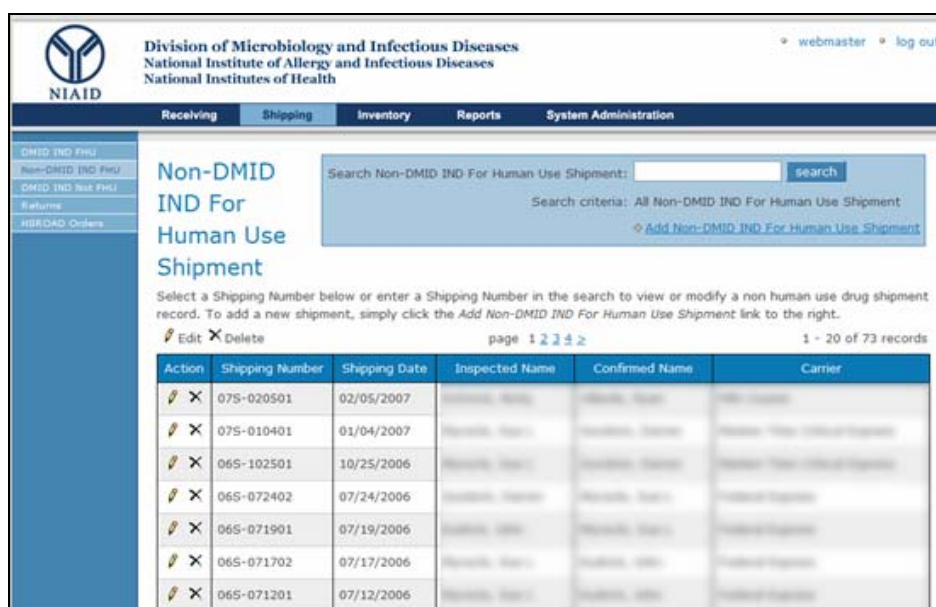
### Non-DMID IND For Human Use Shipments

This area is designed to create, modify, or delete a shipment of Non-DMID IND clinical agents intended for human use. These types of shipments are identified in the system by a series of numbers and the letter “S” to identify it as a shipment. A typical drug shipment number may be 02S-031801. Refer to the previous section - Naming Conventions. These in turn become transactions within the inventory module affecting only the Normal repository.

## Non DMID For Human Use Shipment Report

The Non DMID IND for Human Use Shipment report displays a list of all shipments made from the Repository to clinical sites in the past 3 years subtracting from the normal inventory balance. Completed transactions will have a confirm name visible; uncompleted transactions will not. From this report the user may add a new shipment, edit or delete an existing but yet to be completed transaction. Completed transactions are read only. Users may also search all receipt transactions using the search box or the record set pagination controls.

Data displayed in this report includes the Shipping Number, Shipping Date, the Shipping inspector name, the Shipping confirmation name, and the Carrier Name. An action column is displayed providing icons to edit or delete unconfirmed Non DMID IND For Human Use records



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Receiving Shipping Inventory Reports System Administration

DMID IND FNU  
Non-DMID IND FNU  
DMID IND Test FNU  
Returns  
HSRORD Orders

### Non-DMID IND For Human Use Shipment

Select a Shipping Number below or enter a Shipping Number in the search to view or modify a non human use drug shipment record. To add a new shipment, simply click the Add Non-DMID IND For Human Use Shipment link to the right.

Search Non-DMID IND For Human Use Shipments:

Search criteria: All Non-DMID IND For Human Use Shipment

[Add Non-DMID IND For Human Use Shipment](#)

Edit X Delete page 1 2 3 4 5 1 - 20 of 73 records


Action	Shipping Number	Shipping Date	Inspected Name	Confirmed Name	Carrier
	075-020501	02/05/2007	...	...	...
	075-010401	01/04/2007	...	...	...
	065-102501	10/25/2006	...	...	...
	065-072402	07/24/2006	...	...	...
	065-071901	07/19/2006	...	...	...
	065-071702	07/17/2006	...	...	...
	065-071201	07/12/2006	...	...	...

Figure 10 Non-DMID IND For Human Use Shipment

## Non DMID IND For Human Use Shipment Form

The appropriate form to add, edit or delete a shipment of this type is accessible by clicking the *Add a Non-DMID IND for Human Use Shipment* link, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for Non DMID IND For Human Use shipments. Required fields are denoted by the red line to the right of the form field label.



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Receiving
Shipping
Inventory
Reports
System Administration

[DMID IND FHU](#)  
[Non-DMID IND FHU](#)  
[DMID IND Not FHU](#)  
[Returns](#)  
[HSROAD Orders](#)

## Add Non DMID IND For Human Use Shipment

Shipment Number

DMID Authorization ☐ Yes ☐ No (if Yes, enter a comment below)

Carrier

Protocol No

Protocol Description

IND No

IND Description

IRB Approval ☐ Yes ☐ No

Primary Investigator

AWB Number

Environment

Storage Temperature

Attention To

Site Name

Site Department

Shipping Address 1

Shipping Address 2

Shipping Address 3

City

State/Province

Zip Or Postal Code

Country

Action	Item	Available	Units	Product	Manufacturer	Volume/Unit	Expiration
	1			<input type="text" value="--- Select Product ---"/>		VolurWeig/	

Comments

Inspected By

Note: required fields

**Figure 11 Non DMID IND For Human Use Shipment Form**

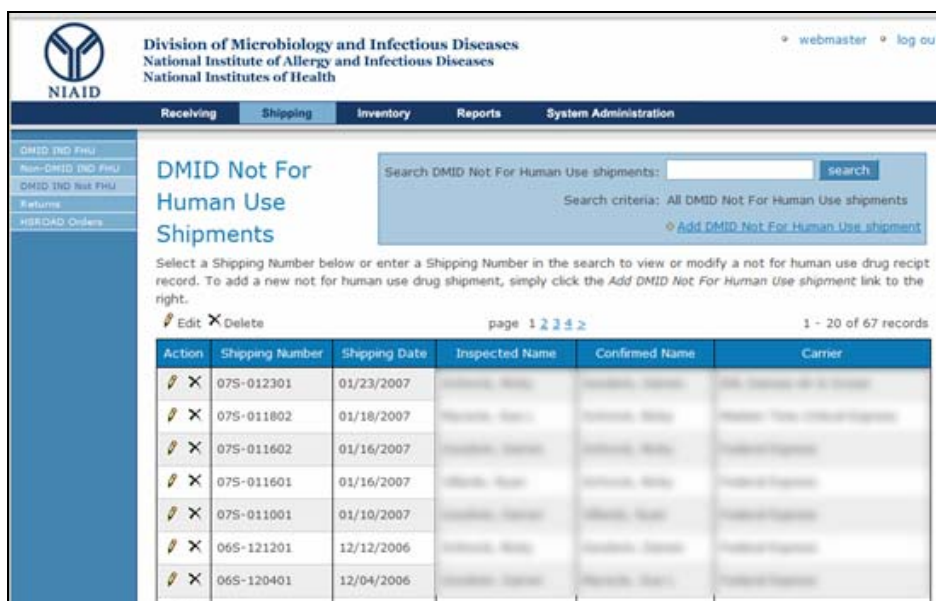
### DMID IND Not For Human Use Shipments

This area is designed to create, modify, or delete a shipment of DMID IND clinical agents not intended for human use. These types of shipments are identified in the system by a series of numbers and the letter “S” to identify it as a shipment. A typical drug shipment number may be 02S-031801. For more information refer to the previous section - Naming Conventions. These in turn become transactions within the inventory module affecting only the Normal repository.

## DMID IND Not For Human Use Shipment Report

The DMID IND Not for Human Use Shipment report displays a list of all Not For Human Use shipments made from the Repository to clinical sites in the past 3 years subtracting from the normal inventory balance. Completed transactions will have a confirm name visible; uncompleted transactions will not. From this report the user may add a new shipment, edit or delete an existing but yet to be completed transaction. Completed transactions are read only. Users may also search all receipt transactions using the search box or the record set pagination controls.

Data displayed in this report includes the Shipping Number, Shipping Date, the Shipping inspector name, the Shipping confirmation name, and the Carrier name. An action column is displayed providing icons to edit or delete unconfirmed DMID IND Not For Human Use records.



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### DMID Not For Human Use Shipments

Select a Shipping Number below or enter a Shipping Number in the search to view or modify a not for human use drug receipt record. To add a new not for human use drug shipment, simply click the [Add DMID Not For Human Use shipment](#) link to the right.

Search DMID Not For Human Use shipments:

Search criteria: All DMID Not For Human Use shipments  
[Add DMID Not For Human Use shipment](#)

Edit Delete page 1 2 3 4 5 1 - 20 of 67 records

Action	Shipping Number	Shipping Date	Inspected Name	Confirmed Name	Carrier
	075-012301	01/23/2007	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi
	075-011802	01/18/2007	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi
	075-011602	01/16/2007	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi
	075-011601	01/16/2007	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi
	075-011001	01/10/2007	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi
	065-121201	12/12/2006	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi
	065-120401	12/04/2006	Heidi, Heidi	Heidi, Heidi	Heidi, Heidi


Figure 12 DMID Not For Human Use Shipments

## DMID IND Not For Human Use Shipment Form

The appropriate form to add, edit or delete a shipment of this type is accessible by clicking the *Add a DMID IND Not for Human Use Shipment* link, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for DMID IND Not For Human Use shipments. Required fields are denoted by the red line to the right of the form field label.





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## Add DMID INDs Not For Human Use Shipment

Shipment Number

Investigator Use Statement On File ☐ Yes ☒ No

Date On Files

Carrier

Primary Investigator

AWB Number

Environment

Storage Temperature

Attention To

Site Name

Site Department

Shipping Address 1

Shipping Address 2

Shipping Address 3

City

State/Province

Zip Or Postal Code

Country

Action	Item	Available	Units	Product	Manufacturer	Volume/Unit	Expiration
	1	<input type="text"/>	<input type="text"/>	<input type="text" value="--- Select Product ---"/>		VolurWeig/	

Comments

Inspected By

Note: required fields

**Figure 13 DMID IND Not For Human Use Shipment Form**

## Return Shipments

This area is designed to create, modify, or delete a shipment of clinical agents to be returned to their manufacturer. These types of shipments are identified in the system by a series of numbers and the letters “RS” to identify it as a return shipment. A typical return drug shipment number may be 02RS-031801. For more information refer to the previous section - Naming Conventions. A transaction within this sub-module will affect the Return Unused and Return Used inventory.

## Return Shipment Report

The Return Shipment report displays a list of all Return drug shipments returned to the manufacturer in the past 3 years affecting the Return Unused and Return Used inventory balance. Completed transactions will have a confirm name visible; uncompleted transactions will not. From this report the user may add a new shipment, edit or delete an existing but yet to

be completed transaction. Completed transactions are read only. Users may also search all receipt transactions using the search box or the record set pagination controls.

Data displayed in this report includes the Shipping Number, Shipping Date, the Shipping inspector name, the Shipping confirmation name, and the Carrier name. An action column is displayed providing icons to edit or delete unconfirmed Return Drug shipments.

Action	Shipping Number	Shipping Date	Inspected Name	Confirmed Name	Carrier
	07RS-033001	03/30/2007			
	07RS-033002	03/30/2007			
	07RS-033003	03/30/2007			
	07RS-032901	03/29/2007			
	07RS-032801	03/28/2007			
	07RS-032601	03/26/2007			

**Figure 14 Return Shipment Report**

### Return Shipment Form

The appropriate form to add, edit or delete a shipment of this type is accessible by clicking the *Add a Return Drug shipment link*, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for Return Drug shipments. Required fields are denoted by the red line to the right of the form field label.



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### Add Return Shipment

Shipment Number

Carrier

Protocol Type ☒ DMID ☐ Non-DMID

**Protocol Information**

DMID Protocol Number

Protocol Short Name

Protocol IND Number

IND Title

AWB Number

Environment

Storage Temperature

Attention To

Shipping Address 1

Shipping Address 2

Shipping Address 3

City

State/Province

Zip Or Postal Code

Country

Action	Item	Available	Units	Inventory	Product	Manufacturer	Volume/Unit	Expiration
	1			Return Unsu	<undefined>		/	

Comments

Inspected By

Note: required fields

**Figure 15 Return Drug Shipment Form**

## HSROAD Orders

This area is designed to as a starting point to fulfill clinical agent orders placed in HSROAD. It is here that orders placed in the HSROAD application are imported into the CARIM application. Once a HSROAD order has been imported, it will be available through the appropriate option based on the transaction type. At this time, the only supported order type that may be placed/fulfilled from HSROAD are DMID IND clinical agents intended for human use trials.

For more information on ordering agents for clinical trials, please refer to the HSROAD system description section on the Order It Module, or the Order It Module System description.

## HSROAD Orders Report

The HSROAD Orders report displays a list of all orders pending import into the system for fulfillment. Transactions of this type affect the normal inventory balance. The only action available in this report is the Import option, once imported these orders are removed from this report and are listed with other transactions in the DMID For Human Report. They will continue to be added by their HSROAD order number. Please refer to the previous section - Naming Conventions for more information. Users may also search all receipt transactions using the search box or the record set pagination controls.


Data displayed in this report includes the Order Number, Protocol Number, Product (ID - Lot - Label); Order Creator, and the Date Ordered. An action column is displayed providing an icon to import the HSROAD order.

Action	Order Number	Protocol Number	Product (ID - Lot - Label)	Ordered By	Date Ordered
Import	06O-050402				05/04/2006
Import	06O-120501				12/05/2006

Figure 16 HSROAD Order Report

## HSROAD Import Form

Clicking the *Import* icon next to the desired record displays the Import HSROAD Order Form. This form displays the order information from the HSROAD order form, related comments, Recipient contact information and required form controls as is defined for HSROAD Order shipments. Required fields are denoted by the red line to the right of the form field label.



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## Import An HSROAD Order Into CARIM

[Comments](#)
[Recipient Contact Information](#)

Order No

070-040504

Exemption To Ship

☐ Yes
 ☒ No

DMID Protocol Number

06-CTIDEM02

Primary Investigator

Munroe, Donna

Carrier

<undefined>

Environment

<undefined>

Storage Temperature

<undefined>

Ordered By

Donna Munroe

Attention To

Sally Strong

Site Name

CTI Test Site

Site Department

Geriatrics Department

Address 1

123456 Golden Pond Way

Address 2

City

Oldsville

State/Province

Virginia

Zip Or Postal Code

89123

Country

U.S.

Quantity	Product	Manufacturer	Volume/Unit
15	M&M's chocolate candy	Unknown	100 gm/Tablet

Comments

Import an HSROAD Order into CARIM

cancel

Note: required fields

### Comments

**Approved (Approved Pending Import)**  
 By: Munroe,Donna  
 Date: 04/05/2007 01:04:41  
 Test Approval

**Created (Pending Approve / Reject)**  
 By: Munroe,Donna  
 Date: 04/05/2007 01:04:17  
 This is a test order for documentation purposes.

### Order Recipient Contact Information

**Site Recipient**  
 Name: Sally Strong  
 Title: Activities Director  
 Phone: 888-888-8801  
 Fax:  
 E-mail: [ss@ctits.nav](mailto:ss@ctits.nav)

**Alternate Site Recipient**  
 Name:  
 Title:  
 Phone:  
 Fax:

Figure 17 HSROAD Order Import Form

## Inventory Module

The Inventory module is used to adjust or transfer the balance of units available from each type of inventory tracked by CARIM. This module can be entered from the Inventory tab on the CARIM main menu (for users that have access to the module). Once the tab is clicked, the user will be presented with a page/module-level menu to each of the individual sub-modules.

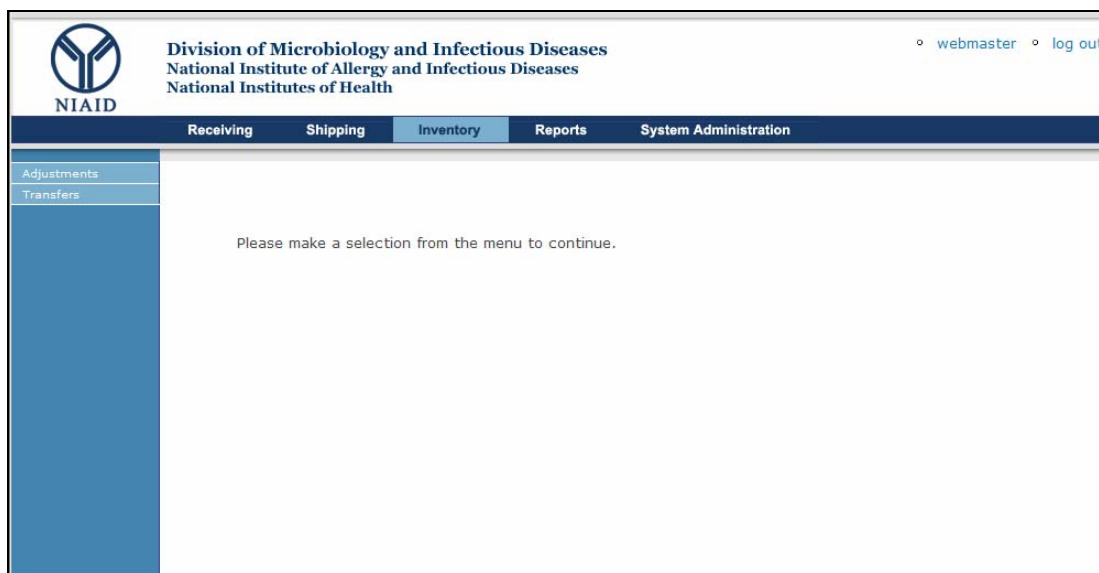


Figure 18 Inventory Module

### Inventory Adjustment

This sub-module was designed to make adjustments to the current inventory tables if an error has occurred and needs to be modified from the original entry. The inventory adjustment module was created in order to avoid changes being made directly on the database. Once a record has been confirmed within the system it cannot be modified. The inventory adjustment form is then useful in order to make the necessary adjustment.

The Inventory adjustment form displays the form controls both required and optional as is defined for making this type of adjustment. Required fields are denoted by the red line to the right of the form field label.

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### DMID-CAR Normal Inventory Adjustment

Adjustment Number

Transaction Date  format: mm/dd/yyyy

Product

Manufacturer

Expiration Date  format: mm/dd/yyyy

Volume/Weight  /

Unit Type

Inventory

Number Of Units Available

Units Adjusted

New Balance

Comments


DMID- CAR Normal Inventory Adjustment

Note: required fields

**Figure 19 Inventory Adjustment Form**

### Internal Transfer Drug Inventory

This sub-module was designed to transfer drug units from one inventory table to another within the database. Sometimes a product has been logged into the wrong repository or its classification needs to be changed. Instead of an adjustment, a simple transfer is in order. Via the transfer form it is as simple as designating the product to transfer, the repository it is being transferred from, the repository it is going to, and the units to be transferred.



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## DMID-CAR Inventory Transfer

Adjustment Number

Transaction Date  format: mm/dd/yyyy

Product

Manufacturer

Expiration Date  format: mm/dd/yyyy

Volume/Weight  /

Unit Type

---

From Inventory

Number Of Units Available

New Balance

---

To Inventory

Number Of Units Available

New Balance

---

Units To Transfer

Comments

DMID-CAR Inventory Transfer

cancel

Note: required fields

Figure 20 Inventory Transfer Form

## Reports Module

The Report module is used to display reports of the information from the CARIM database, such as receivables, shipments, inventory, etc. This module can be entered from the CARIM main menu for users that have access to it. The user will be presented with a links menu to each of these individual reports group by categories. Those categories are:

- ✓ Receiving
- ✓ Shipping
- ✓ Inventory
- ✓ Product
- ✓ Summary



**Figure 21 Reports Module**

Each report has features such as searches, sorting, and printing. The search box allows for searches by a text string or by date range. Reports in tabular format can be sorted by clicking on column headers. Clicking on the Print Preview Button will take the user to a printable version of the report, which will not have any of the navigation bars and will have all records for the report on a single page. The user will have the ability to print their selected report via the browser window print option.

## Receiving Reports

These reports provide historical information on all transactions related to Normal and Return receipts. The system maintains three years of historical data which can be searched by text, dates or product labels within the report. Detailed information on any receipt can be viewed by clicking the Receipt Number link.

### Receiving Normal Report

The Receiving Normal report lists the normal receipts and their respective information. The report displays the following information fields per Receipt number:

- ✓ Receipt Number
- ✓ Confirmed Date
- ✓ Product (Product ID - Lot Number - Label Number)
- ✓ Volume per Container
- ✓ Received
- ✓ Quarantined
- ✓ Rejected

Receipt No.	Confirm Date	Product (ProductID - Lot Number - Label Name)	Vol per Cont	Received	Quarantined	Rejected
<a href="#">07R-030801</a>	03/08/2007	07R-030801-001-001-001	/Kit	20	0	0
<a href="#">07R-030101</a>	03/01/2007	07R-030101-001-001-001	2 ml/Vial	400	0	0
<a href="#">07R-022801</a>	02/28/2007	07R-022801-001-001-001	10 ml/Vial	400	0	0
<a href="#">07R-022601</a>	02/26/2007	07R-022601-001-001-001	0.5 ml/Vial	3,000	0	0
<a href="#">07R-021501</a>	02/16/2007	07R-021501-001-001-001	100 doses/Kit	60	0	0
<a href="#">07R-020502</a>	02/05/2007	07R-020502-001-001-001	30 mg/Vial	0	45	0
<a href="#">07R-020502</a>	02/05/2007	07R-020502-001-001-001	0.75 mg/Vial	0	45	0
<a href="#">07R-020501</a>	02/05/2007	07R-020501-001-001-001	1 ml/Vial	0	68	0
<a href="#">07R-012901</a>	01/29/2007	07R-012901-001-001-001	0.50 ml/Vial	10	0	0
<a href="#">07R-012501</a>	01/25/2007	07R-012501-001-001-001	/Needle	500	0	0

Figure 22 Receiving Normal Report

### Receiving Return Report

The Receiving Return report lists the returned receipts and their respective information. The report displays the following information fields per Receipt number:

- ✓ Receipt number
- ✓ IND Number/Protocol Number
- ✓ Protocol Investigator/Site



- ✓ Product ( Product ID - Lot Number - Label Number)
- ✓ Volume per Container
- ✓ Units Returned Used
- ✓ Units Returned Unused
- ✓ Units Quarantined

Receipt No.	IND/Protocol	PI / Site	Product (ProductID - Lot Number - Label Name)	Vol per Cont	Units Returned Used	Units Returned Unused	Units Quarantined
07RR-032901				100 ml/Vial	0	10	0
07RR-032802				100 ml/Vial	0	21	0
07RR-032801				100 ml/Vial	0	35	0
07RR-032601				100 ml/Vial	0	20	0
07RR-032302				100 ml/Vial	32	0	0

**Figure 23 Receiving Return Report**

## Shipping Reports

These reports provide historical information on all shipments made by Product type. The system maintains three years of historical data which can be searched by text, dates or product labels within the report. Detailed information on any shipment can be viewed by clicking the Ship Number link.

### DMID For Human Use Shipment Report

The DMID for Human Use Shipment report lists the DMID IND shipments for Human Use agents and their respective information. The report displays the following information fields per shipment number:

- ✓ Shipment Number
- ✓ Confirm Date
- ✓ IND Number/Protocol Number
- ✓ PI /Performance Site
- ✓ Units Shipped
- ✓ Product (Product ID - Lot Number - Label Number)
- ✓ Unit Type

Ship Number	Confirm Date	IND / Protocol	PI / Performance Site	Units Shipped	Product (ProductID - Lot Number - Label Name)	Unit Type
<a href="#">07Q-040501</a>	04/05/2007	07Q-040501	07Q-040501	1	07Q-040501-001-001	Vial
<a href="#">07Q-040501</a>	04/05/2007	07Q-040501	07Q-040501	1	07Q-040501-001-001	Vial
<a href="#">07Q-040501</a>	04/05/2007	07Q-040501	07Q-040501	1	07Q-040501-001-001	Vial
<a href="#">07Q-040201</a>	04/03/2007	07Q-040201	07Q-040201	1	07Q-040201-001-001	Kit
<a href="#">07Q-040201</a>	04/02/2007	07Q-040201	07Q-040201	1	07Q-040201-001-001	Kit
<a href="#">07Q-032202</a>	03/22/2007	07Q-032202	07Q-032202	1	07Q-032202-001-001	Kit

**Figure 24 DMID For Human Use Shipment Report**

### NON-DMID For Human Use Shipment Report

The NON-DMID for Human Use Shipment report lists the NON-DMID shipments for Human Use agents and their respective information. The report displays the following information fields per shipment number:

- ✓ Shipment Number
- ✓ Confirm Date
- ✓ PI /Performance Site
- ✓ Product (Product ID - Lot Number -Label Name)
- ✓ Units Shipped
- ✓ Unit Type

The screenshot shows a web application interface for the Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health. The main navigation bar includes 'Receiving', 'Shipping', 'Inventory', 'Reports', and 'System Administration'. The left sidebar lists various report categories: 'Receiving', 'Shipping', 'DMID IND PMU', 'Non-DMID IND PMU', 'DMID IND Not PMU', 'Returns', 'Inventory', 'Product', 'Summary', and 'Alerts'. The main content area is titled 'Non-DMID IND For Human Use Shipment Report' and includes a search form with fields for 'Search text', 'From (mm/dd/yyyy)', 'To (mm/dd/yyyy)', and 'Product Label'. Below the search form, a table displays shipment records. The table has columns for 'Ship Number', 'Confirm Date', 'PI / Performance Site', 'Product (ProductID - Lot Number - Label Name)', 'Units Shipped', and 'Unit Type'. The table shows 15 records, with the first 8 visible in the screenshot. A 'Print Page' button is located in the top right corner of the report area.


Ship Number	Confirm Date	PI / Performance Site	Product (ProductID - Lot Number - Label Name)	Units Shipped	Unit Type
075-020501	02/05/2007				Vial
075-010401	01/04/2007				Kit
075-010401	01/04/2007				Vial
065-102501	10/25/2006				Vial
065-102501	10/25/2006				Kit
065-072402	07/24/2006				Vial
065-072402	07/24/2006				Syringe

**Figure 25 Non DMID For Human Use Report**

### **DMID Not For Human Use Shipment Report**

The DMID Not for Human Use shipment report lists the DMID shipments Not For Human Use agents and their respective information. The report displays the following information fields per return shipment number:

- ✓ Shipment Number
- ✓ Confirm Date
- ✓ PI /Performance Site
- ✓ Product (Product ID - Lot Number -Label Name)
- ✓ Units Shipped
- ✓ Container



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Print Page

Search text

From (mm/dd/yyyy)

To (mm/dd/yyyy)

Product Label

search

Page: 1 2 3 4 5 6 7

1 - 20 of 116 records

Ship Number	Confirm Date	PI / Performance Site	Product (ProductID - Lot Number - Label Name)	Units Shipped	Container
<a href="#">07S-012301</a>	01/23/2007			72	Vial
<a href="#">07S-012301</a>	01/23/2007			496	Vial
<a href="#">07S-011802</a>	01/18/2007			4	Bottle
<a href="#">07S-011602</a>	01/16/2007			22	Vial
<a href="#">07S-011601</a>	01/16/2007			7	Vial
<a href="#">07S-011001</a>	01/10/2007			520	Vial
<a href="#">06S-121201</a>	12/12/2006			130	Vial
<a href="#">06S-120401</a>	12/04/2006			6	Bottle
<a href="#">06S-101602</a>	10/16/2006			5	Vial
<a href="#">06S-101601</a>	10/16/2006			5	Vial

**Figure 26 DMID IND Not For Human Use Shipment Report**

### Return Shipment Report

The Return Shipment report lists the DMID returned shipments to manufacturers and their respective information. The report displays the following information fields per return shipment number:

- ✓ Shipment Number
- ✓ Confirm Date
- ✓ IND Number/Protocol Number
- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Units Returned Used
- ✓ Units Returned Unused
- ✓ Unit Type



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Search text

From (mm/dd/yyyy)

To (mm/dd/yyyy)

Product Label

search

Print Page

Page: 1 2 3 4 5 6 7 8

1 - 20 of 134 records

Ship Number	Confirm Date	IND / Protocol	Product (ProductID - Lot Number - Label Name)	Manufacturer	Units Returned Used	Units Returned Unused	Unit Type
<a href="#">0785-033003</a>	03/30/2007	N/A / N/A			0	150	Vial
<a href="#">0785-033002</a>	03/30/2007	N/A / N/A			0	8	Bottle
<a href="#">0785-033001</a>	03/30/2007	N/A / N/A			0	5	Bottle
<a href="#">0785-032901</a>	03/29/2007	BB-11143 / 03-107			0	10	Vial
<a href="#">0785-032801</a>	03/28/2007	BB-11143 / 03-107			0	56	Vial
<a href="#">0785-032601</a>	03/26/2007	BB-11143 / 03-107			0	20	Vial

Figure 27 Return Shipment Report

## Inventory Reports

These reports provide historical information on all Inventory adjustments and transfers made to all repository balance for the past three years. Reports are categorized by repository type for easy access. These reports can be searched by text and product label via the search option available in each report.

### Inventory Normal Report

The Inventory Normal Report lists the balances for all Normal product receipts in the repository. The report displays the following information fields:

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Unit Type
- ✓ Current Balance
- ✓ Expiration Date

Product (ProductID - Lot Number - Label Name)	Manufacturer	Unit Type	Current Balance	Expiration Date
...	...	Vial	400	06/01/2008
...	...	Vial	400	10/01/2008
...	...	Vial	2,840	
...	...	Kit	58	05/31/2007
...	...	Vial	30	08/31/2008
...	...	Vial	30	03/31/2008
...	...	Vial	45	02/28/2008
...	...	Needle	480	03/31/2009

Figure 28 Normal Inventory Report

### Inventory Return Used Report

The Inventory Return Used Report lists the balances for all returned used products in the repository. The report displays the following information fields:

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Unit Type
- ✓ Current Balance
- ✓ Expiration Date

Product (ProductID - Lot Number - Label Name)	Manufacturer	Unit Type	Current Balance	Expiration Date
...	...	Vial	34	12/31/2005
...	...	Vial	10	
...	...	Vial	22	

Figure 29 Inventory Return Used Report

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Unit Type
- ✓ Current Balance
- ✓ Expiration Date

### Figure 30 Inventory Return Unused Report

The Inventory Quarantine Report lists the balances for all products in quarantine in the repository. The report displays the following information fields:

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Unit Type
- ✓ Current Balance
- ✓ Expiration Date

Product (ProductID - Lot Number - Label Name)	Manufacturer	Unit Type	Current Balance	Expiration Date
...	...	Vial	270	
...	...	Vial	80	
...	...	Vial	37	
...	...	Bottle	1	
...	...	Applicator	28	11/30/2007

Figure 31 Inventory Quarantine Report

### Inventory Summary Report

The Inventory Summary Report lists the balances for all products in the repositories. The report displays the following information fields:

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Normal Balance
- ✓ Return Used Balance
- ✓ Return Unused Balance
- ✓ Quarantine Balance
- ✓ Current Total Balance
- ✓ Unit Type
- ✓ Expiration Date

Product (ProductID - Lot Number - Label Name)	Normal Balance	Return Used Balance	Return Unused Balance	Quarantine Balance	Current Total Balance	Unit Type	Expiration Date
...	...	0	0	0	400	Vial	06/01/2008
...	...	0	0	0	400	Vial	10/01/2008
...	...	0	0	0	2,840	Vial	

Figure 32 Inventory Summary Report



## Return Report

The Return Drug Inventory Report lists the balances for all returned and rejected products in the repository. The report displays the following information fields:

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Returned Balance
- ✓ Rejected Balance
- ✓ Expiration Date

Product (ProductID - Lot Number - Label Name)	Manufacturer	Returned Balance	Rejected Balance	Expiration Date
...	...	0	2,000	
...	...	0	1	
...	...	0	1	01/01/2008
...	...	0	160	
...	...	112	222	

**Figure 33 Return Drug Inventory Report**

## Inventory Adjustments Report

The Inventory Adjustments Report lists all adjustments made within the repository. The report displays the following information fields: This report can be searched by text, From and To dates and also Product Label.

- ✓ Adjustment Number
- ✓ Adjustment Date
- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Manufacturer
- ✓ Expiration Date
- ✓ Inventory
- ✓ Units Available
- ✓ Units Adjusted
- ✓ New Balance



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Receiving
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- Receiving
- Shipping
- Inventory
- Normal
- Return Used
- Return Unused
- Quarantine
- Inventory Summary
- Return
- Adjustments
- Transfer
- Product
- Summary
- Alerts

## Inventory Adjustments Report

 [Print Page](#)

Search text

From  
(mm/dd/yyyy)

To  
(mm/dd/yyyy)

Product Label

search

Page: 1 2 3 >
1 - 20 of 52 records

Adjustment No	Adjustment Date	Product (ProductID - Lot Number - Label Name)	Manufacturer	Expiration Date	Inventory	Units Available	Units Adjusted	New Balance
07A-030203	03/02/2007	...	...	03/11/2004	Return Unused	278	-139	139
Comments: Duplicate transfer. SM								
07A-020602	02/06/2007	...	...	03/31/2009	Normal	500	-20	480
Comments: 20 needles taken to Investigator's Meeting								
07A-020601	02/06/2007	...	...	06/01/2007	Normal	215	-25	190
Comments: One pack of 25 vials taken to Investigators Meeting								

Figure 34 Inventory Adjustment Report

### Inventory Transfer Report

The Inventory Transfer Report lists all transfers made between the repositories. The report displays the following information fields:

- ✓ Adjustment Number
- ✓ Adjustment Date
- ✓ Product (
- ✓ Manufacturer
- ✓ Expiration Date
- ✓ From Inventory
- ✓ To Inventory
- ✓ Units Transferred
- ✓ Comments

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Receiving Shipping Inventory Reports System Administration

Inventory Transfer Report

Search text: From (mm/dd/yyyy) To (mm/dd/yyyy) Product Label search

Page: 1 2 3 4 5 6 7 8 9 10 > 22 1 - 20 of 444 records

Adjustment No	Adjustment Date	Product (ProductID - Lot Number - Label Name)	Manufacturer	Expiration Date	From Inventory	To Inventory	Units Transferred
07T-033004	03/30/2007			04/30/2005	Normal		-10
Comments: Product is expired. Transfer balance to quarantine status pending destruction. MH 30Mar07							
07T-033004	03/30/2007			04/30/2005		Quarantine	10
Comments: Product is expired. Transfer balance to quarantine status pending destruction. MH 30Mar07							
07T-033003	03/30/2007			04/01/2007	Normal		-150
Comments: Product expiring. To be destroyed. 30MAR07 SM							

Figure 35 Inventory Transfer Report

## Product Reports

The Product Reports provided historical information on all confirmed transactions by transaction type. Transaction reports are provided for the Normal Return Used, Return Unused and Quarantine Inventory transactions and also Product reports by Protocol and Expiration dates. Each report can be search by Text, From and To dates and Product label.

### Transactions Report - Normal Inventory

The Product Transactions Report - Normal Inventory lists all the confirmed transactions which affected the Normal Inventory in CARIM. The report displays the following information fields:

- ✓ Transaction Date
- ✓ Transaction Number
- ✓ Transaction Type
- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Units
- ✓ Balance

### Transaction Repot - Return used

- ✓ Transaction Date
- ✓ Transaction Number
- ✓ Transaction Type
- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Units
- ✓ Balance



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Receiving
Shipping
Inventory
Reports
System Administration

Receiving  
Shipping  
**Inventory**  
Product  
Transactions Normal  
Transactions Return Used  
Transactions Return Quarantined  
Transactions Quarantined  
Summary  
Alerts

## Product Transactions Report -Return Used Inventory

From (mm/dd/yyyy) To (mm/dd/yyyy)

Product Label

[Print Page](#)

Page: 1 2 3 4 5 6 >
1 - 20 of 115 records

Transaction Date	Transaction No	Transaction Type	Product (ProductID - Lot Number - Label Name)	Units	Balance
03/23/2007	<a href="#">07RS-032302</a>	Shipping Return	(RS - 032302) - [Redacted]	-77	
03/23/2007	<a href="#">07RR-032302</a>	Receiving Return	(RR - 032302) - [Redacted]	32	
03/23/2007	<a href="#">07RR-032301</a>	Receiving Return	(RR - 032301) - [Redacted]	45	
03/15/2007	<a href="#">07RS-031501</a>	Shipping Return	(RS - 031501) - [Redacted]	-91	

**Note: Printed material considered to be uncontrolled** 45

### Transaction Report - Return Unused

The Product Transactions Report - Return Unused lists all the confirmed transactions which affected the Return Unused Inventory in CARIM. The report displays the following information fields:

- ✓ Transaction Date
- ✓ Transaction Number
- ✓ Transaction Type
- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Units
- ✓ Balance

Transaction Date	Transaction No.	Transaction Type	Product (ProductID - Lot Number - Label Name)	Units	Balance
03/30/2007	0785-033002	Shipping Return	...	-150	
03/30/2007	077-033002	Transfer	...	150	
03/30/2007	0785-033002	Shipping Return	...	-8	
03/30/2007	0785-	Shipping Return	...	-5	

**Figure 38 Product Transaction Report - Return Unused Inventory**

### Transaction Report - Quarantined

The Product Transactions Report - Quarantined Inventory lists all the confirmed transactions which affected the Quarantine Inventory in CARIM. The report displays the following information fields:

- ✓ Transaction Date
- ✓ Transaction Number
- ✓ Transaction Type
- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Units
- ✓ Balance

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Receiving Shipping Inventory **Reports** System Administration

Product Transactions Report - Quarantine Inventory

Print Page

Search text From (mm/dd/yyyy) To (mm/dd/yyyy) Product Label search

Page: 1 2 3 4 5 6 7 8 > 1 - 20 of 158 records

Transaction Date	Transaction No	Transaction Type	Product (ProductID - Lot Number - Label Name)	Units	Balance
03/30/2007	07T-033004	Transfer	...	10	10
03/23/2007	07T-032302	Transfer	...	2,000	0
03/23/2007	07T-032301	Transfer	...	2,000	2,000
03/06/2007	07T-	Transfer	...	-343	0

**Figure 39 Product Transaction Report - Quarantine Inventory**

### Product Protocols Report

The Product Protocol Report lists all the confirmed transactions by Protocol number/Protocol short Name. The report displays the following information fields:

- ✓ Product (Product ID - Lot Number - Label Name)
- ✓ Expiration Date
- ✓ Protocol Number/Short Name

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Receiving Shipping Inventory **Reports** System Administration

Product Protocols Report

Print Page

Search text From (mm/dd/yyyy) To (mm/dd/yyyy) Product Label search

Page: 1 2 3 4 5 6 7 8 9 10 > >> 1 - 20 of 256 records

Product (ProductID - Lot Number - Label Name)	Expiration Date	Protocol Number/Short Name
...	...	...
...	...	...
...	...	...
...	...	...

**Figure 40 Product Protocol Report**

## Summary Reports

The Summary Reports provide quick reference to summary totals for Return, Return Used and Shipped transactions. Each report provides totals with no links for accessing detailed information. Transactions can be searched by date range.

### Receiving Normal Summary Report

The Receiving Normal Summary report lists the total of normal receipts. The report displays the following information fields:

- ✓ Receipts Total
- ✓ Total Units Received
- ✓ Total Units Quarantined
- ✓ Total Units Rejected

Receipts Total	Total Units Received	Total Units Quarantined	Total Units Rejected
541	665,659	2,736	25

**Figure 41 Receiving Normal Summary Report**

### Receiving Return Summary Report

The Receiving Return Summary report lists the total of returned receipts. The report displays the following information fields:

- ✓ Receipts Total
- ✓ Total Units Received
- ✓ Total Used
- ✓ Total Units Quarantined

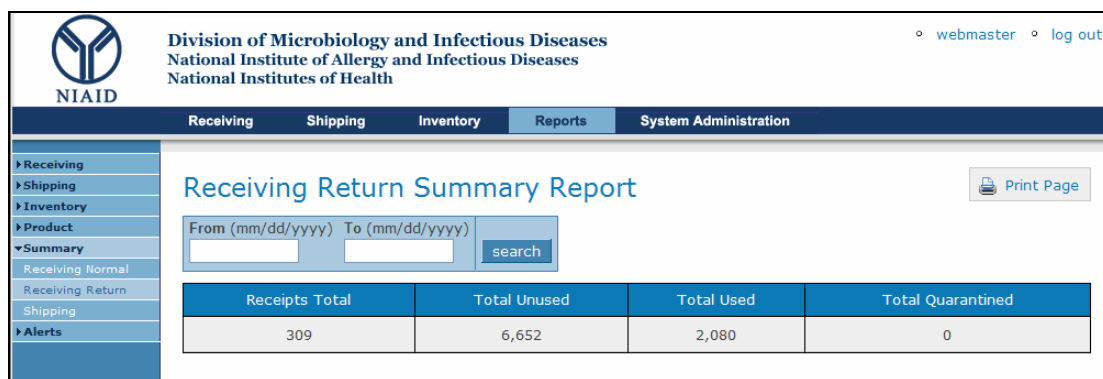


Figure 42 Receiving Return Summary Report

### Shipping Summary Report

The Shipping Summary report lists totals of all shipments for investigational use, not for human use and return drug types. The report displays the following information fields:

- ✓ Shipment Type
- ✓ Total Shipments
- ✓ Total Sites
- ✓ Total Units Shipped

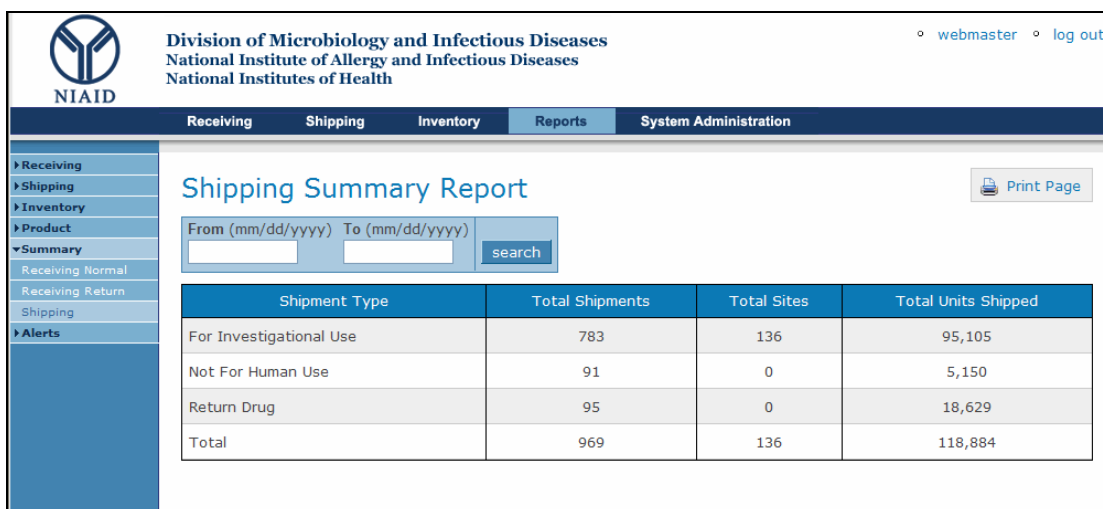


Figure 43 Shipping Summary Report

### Alerts

Alerts or Email notifications are generated when certain events occur within the systems. These events include advices sent to Order Creators and associated personnel for performance site when their placed orders have been confirmed and shipped to the performance site. Scheduled nightly task generate Product Expiry email alerts which advise system users of those products



which will expire in either 60 or 42 days. Archive email alerts are also included in the nightly task run and will archive all transactions which meet the following criterion:

Archive Products, Shipments and Receipts Criteria:

- ✓ Products with 0 balance for more than 180 days
- ✓ Shipments which have been confirmed for more than 1095 days
- ✓ Receipts confirmed for more than 1095 days

## Alert Log

The alert log report displays a list of all email notifications sent from the CARIM application. The report displays the following information fields:

- ✓ Alert #
- ✓ Sent To
- ✓ Sent From
- ✓ Subject
- ✓ Attachment
- ✓ Date of Attempted Send

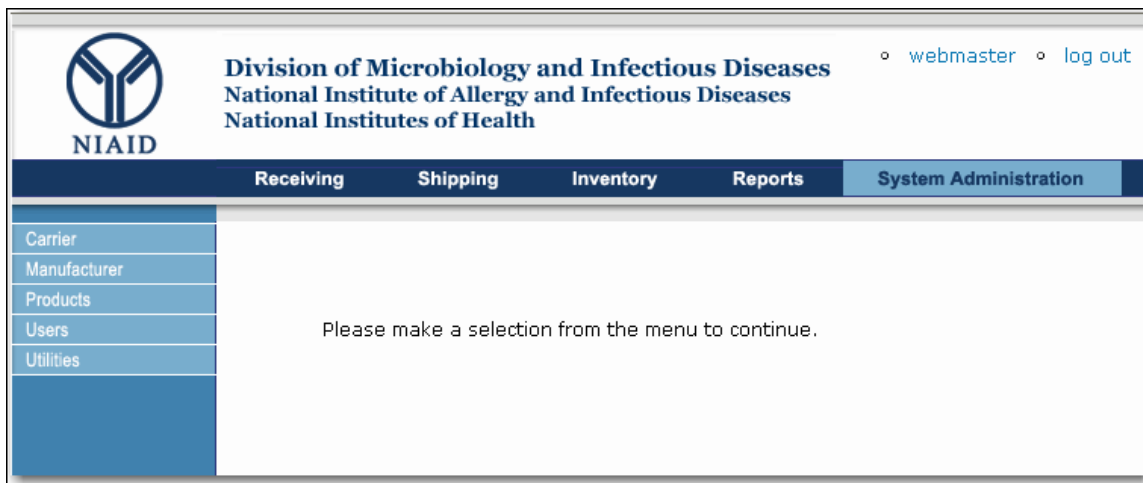
Clicking the subject of each report allows the user to view the details of the specific alert chosen. The details will display all information retained about the email notification, including a recipient list, subject, body, name of any attachments, format, and attempted send date.

Alert #	Sent To	Sent From	Subject	Attachment	Date of attempted send
102			[system test] Order has been shipped (070-040501)	Yes	04/05/2007 12:29:10 PM
101			Order has been shipped (070-040301)	Yes	04/03/2007 11:53:04 AM
100			Order has been shipped (070-040201)	Yes	04/02/2007 02:14:32 PM

Figure 44 Alert Log

## System Administration Module

The System Administration Module is used to create, edit, or delete the carriers, manufacturers, products, users, and look-up table values used throughout the system. This module can be entered from the CARIM main menu for users that have administrative access. The user will be presented with a links menu to each of the individual sub-modules for the system administration module.



### Carrier

This sub-module is used to create, modify, or delete the carrier's information for the drugs received or shipped within the CARIM system. The carriers entered via this sub-module populate the drop-down lists within the application.

### CARIM Carriers Report

The CARIM Carriers report displays a list of all Carriers currently entered into the system. Users may also search records using the search box or the record set pagination controls.

Data displayed in this report includes the Action, Carrier, Address; Contact Name, Phone number, Fax number, Email and Archived. An action column is displayed providing icons to edit or delete entered records.

Action	Carrier	Address	Contact Name	Phone Number	Fax Number	E-mail
	Air Freight Expeditors	PO Box 16804 Washington, DC 20041 U.S.		703-661-3650		
	Airborne Express	30 Southlawn Ct, Southlawn Lane and Southlawn Ct Rockville, MD 20850 U.S.		1800 247 2676		
	Airnet Systems, Inc.	3939 International Gateway Columbus, OH 43219 U.S.	Eric Indress	1800 999 0974		

Figure 45 CARIM Carriers Report

### Add a New Carrier Form

The appropriate form to add, edit or delete a Carrier record is accessible by clicking the *Add a New Carrier link*, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for adding Carriers to the system. Required fields are denoted by the red line to the right of the form field label.

Company Name:

Address 1:

Address 2:

City:

State:

Zip / Postal Code:

Country:

Contact Name:

Contact Telephone Number:

Contact Fax Number:

Contact E-Mail Address:

Note: required fields

Figure 46 Add a Carrier Form

## Manufacturer

This sub-module is used to create, modify, or delete the manufacturer's information for the drugs received or shipped within the CARIM system. The manufacturers entered via this sub-module populate the drop-down lists within the application.

### CARIM Manufacturers Report

The CARIM Manufacturers report displays a list of all Manufacturers entered into the system. Users may also search records using the search box or the record set pagination controls.

Data displayed in this report includes the Action, Manufacturer, Address; Contact Name, Phone number, Fax number, Email and Archived. An action column is displayed providing icons to edit or delete entered records.

Action	Manufacturer	Address	Contact Name	Phone Number	Fax Number	E-mail

Figure 47 CARIM Manufacturer's Report

### Add a Manufacturer Form

The appropriate form to add, edit or delete a Manufacturer record is accessible by clicking the *Add a New Carrier link*, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for adding a Manufacturer to the system. Required fields are denoted by the red line to the right of the form field label.

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Receiving Shipping Inventory Reports **System Administration**

Carrier  
Manufacturer  
Products  
Users  
Utilities

Add A Manufacturer

Company Name:

Address 1:

Address 2:

City:

State:

Zip / Postal Code:

Country:

Contact Name:

Contact Telephone Number:

Contact Fax Number:

Contact E-Mail Address:

Create Cancel

Note: required fields

**Figure 48 Add a Manufacturer Form**

## Products

This sub-module is used to create, modify, or delete all received or shipped product information within the CARIM system. Products are associated with the respective protocols and made accessible to HSROAD users via the Order It module with the Display in HSROAD options. Products with this option set to No will not be visible in the product list for a particular protocol. For more information on Ordering products through the Order it Module please refer to the either the Order it Module section of the HSROAD System Description or the Order it Module System Description. The products entered via this sub-module populate the drop-down lists within the application.

### CARIM Products List Report

The CARIM Product List report displays a list of all products entered into the system both in use and archived. Users may also search records using the search box or the record set pagination controls.

Data displayed in this report includes the Action, Product (Product ID - Lot Number - Label Name), Container (Volume Weight/Unit Type); Manufacturer Name, Expiration Date, Archived, and Display in HSROAD. An action column is displayed providing icons to edit or delete entered records.

Action	Product (ProductID - Lot Number - Label Name)	Container (volume weight/unit type)	Manufacturer Name	Expiration Date	Archived	Display in HSRDAD
				06/01/2008	No	Yes
				10/01/2008	No	Yes
				N/A	No	Yes
				05/31/2007	No	Yes

Figure 49 CARIM Products List Report

### Create a New Product Form

The appropriate form to add, edit or delete a Product record is accessible by clicking the *Add a New Product* link, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for adding Products to the system. Required fields are denoted by the red line to the right of the form field label.

Figure 50 Create a New Product Form

## Users

This sub-module is used to create, modify, or delete all pertinent information for the users with access to the CARIM system. Those users with access to this module have the ability to reset user passwords and send an alert to the affected user advising of the change. System permissions are set in this module and consist of three levels. These levels include:

- ✓ Read Only
- ✓ Read & Write
- ✓ Reports

### CARIM Users Report

The CARIM Users report displays a list of all users and user account information that have access to the system. Users may also search records using the search box or the record set pagination controls.

Data displayed in this report includes the Action, User ID, Name; E-mail, Last Login Date, Read Only, Read & Write and Reports. An action column is displayed providing icons to edit or delete existing records.

Action	User ID	Name	E-mail	Last Login Date	Read Only	Read & Write	Reports
	1	John Doe	john.doe@nih.gov	06/23/2004	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	2	Jane Smith	jane.smith@nih.gov	08/01/2006	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	3	Mark Lee	mark.lee@nih.gov	07/20/2006	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	4	Pat Jones	pat.jones@nih.gov	04/04/2007	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	5	Robert White	robert.white@nih.gov	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Figure 51 CARIM User Report

### Create a new User Form

The appropriate form to add, edit or delete a user record is accessible by clicking the *Create a new user link*, clicking the edit icon, or clicking the delete icon next to the desired record.

This form displays the form controls required and optional as is defined for adding Products to the system. Required fields are denoted by the red line to the right of the form field label.

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Receiving Shipping Inventory Reports **System Administration**

Carrier  
Manufacturer  
Products  
Users  
Utilities

Add A New User

User ID

Password

First Name

Last Name

Middle Initial

E-Mail Address

Address

City

State/Province

ZIP / Postal Code

Telephone  Note: numbers only

Telephone Extension  Note: numbers only

Fax  Note: numbers only

Privileges ☐ Read only  
☐ Read, write  
☐ Reports

Reset Password ☐ Check here to reset this user's password and send this user a reset email alert

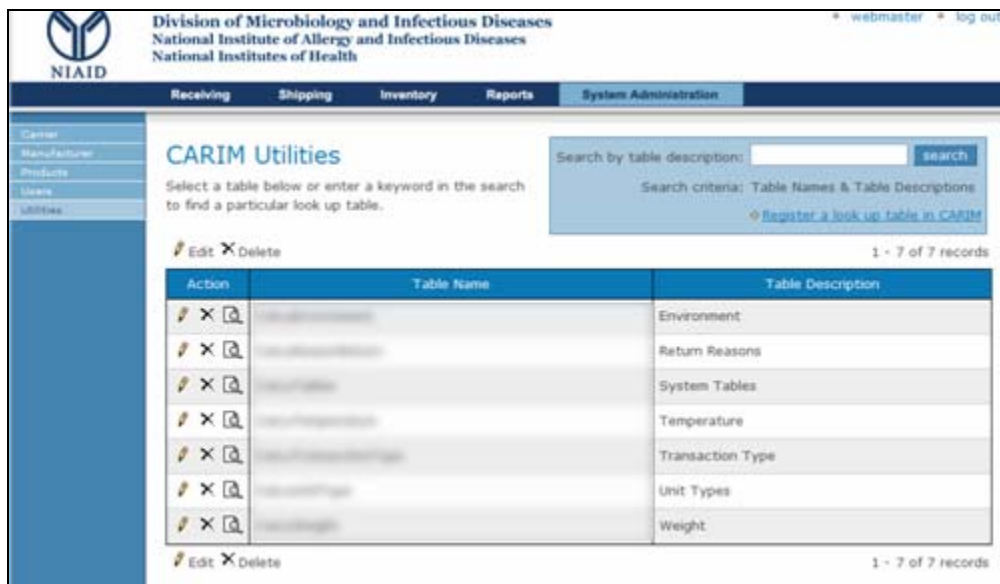
Note: required fields

Figure 52 Add a New User Form

## Utilities

The Utilities module is used to edit the Lookup tables for the application. This module can be entered from the System Administration Module for users with administrative access. Upon entering the Utilities module, the administrator will be presented with a table listing all the available for edit lookup tables in the system. The tables can be sorted by the table name or description, or the user can search for a table by entering a portion of the table description in the search box. Upon choosing a lookup table, the user will then have the option to edit, delete, or add records to the table.





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Receiving Shipping Inventory Reports **System Administration**

Center  
Manufacturer  
Products  
Users  
Utilities

## CARIM Utilities

Select a table below or enter a keyword in the search to find a particular look up table.

Search by table description:

Search criteria: Table Names & Table Descriptions  
[Register a look up table in CARIM](#)

1 - 7 of 7 records

Action	Table Name	Table Description
	Environment	Environment
	Return Reasons	Return Reasons
	System Tables	System Tables
	Temperature	Temperature
	Transaction Type	Transaction Type
	Unit Types	Unit Types
	Weight	Weight

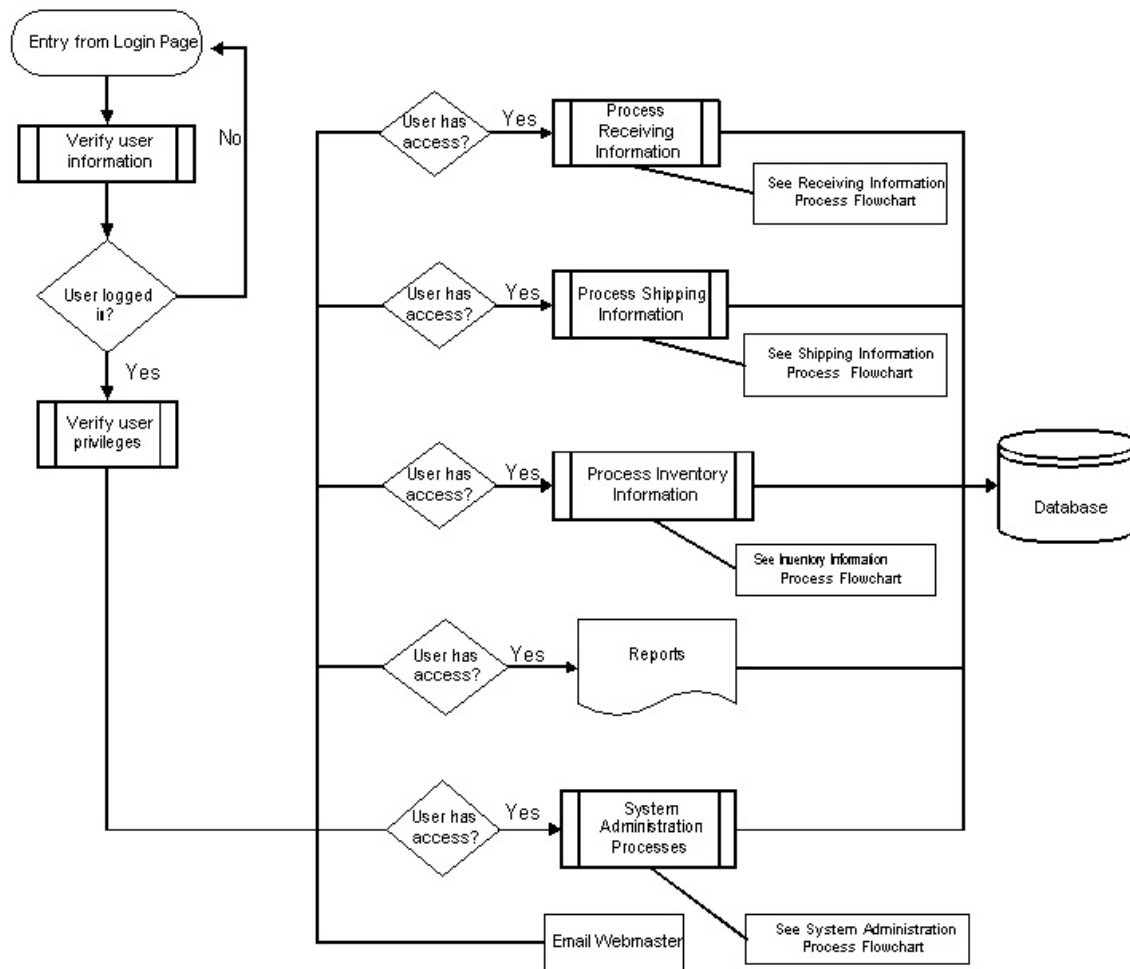
1 - 7 of 7 records

**Figure 53 CARIM Utilities**

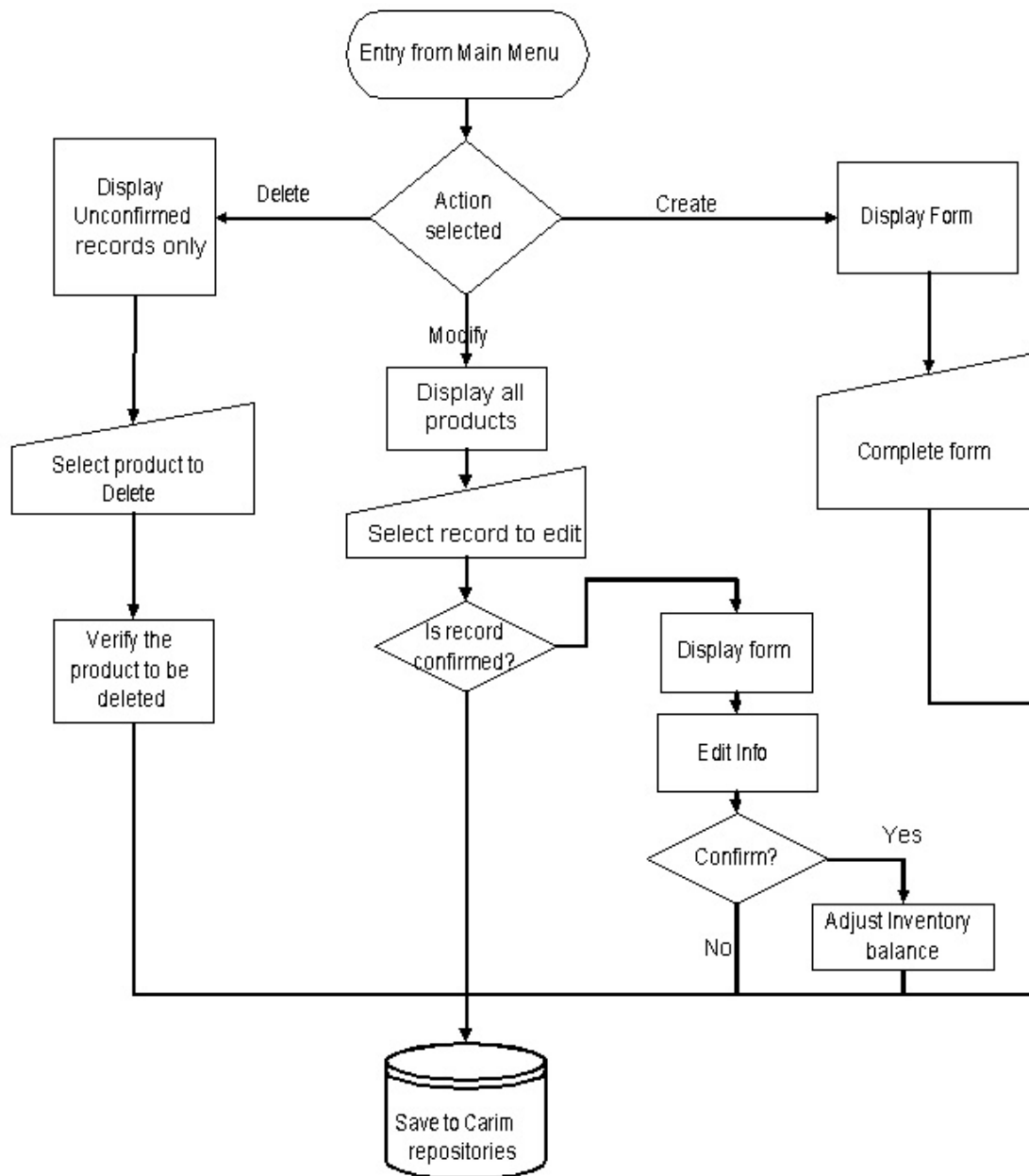
Please note that the LuTables (Look Up tables) perform a different function. Adding or editing the records in these tables will affect the data displayed within the system. Edits made to the table names will only affect the Utilities Module, and will not remove or change the table names in the database.

## Appendix – Functional Process Flowcharts

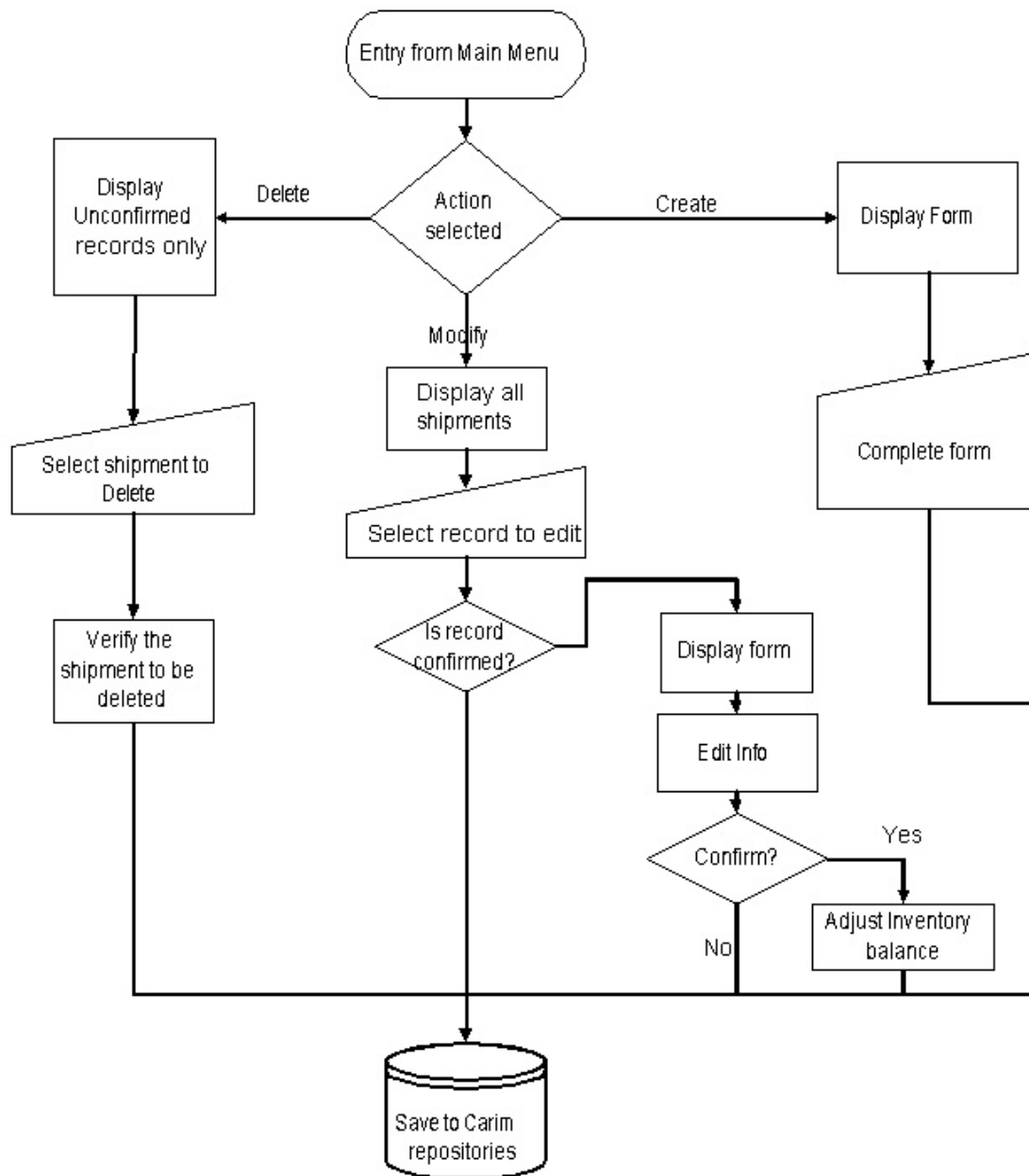
CARIM High Level System Flowchart



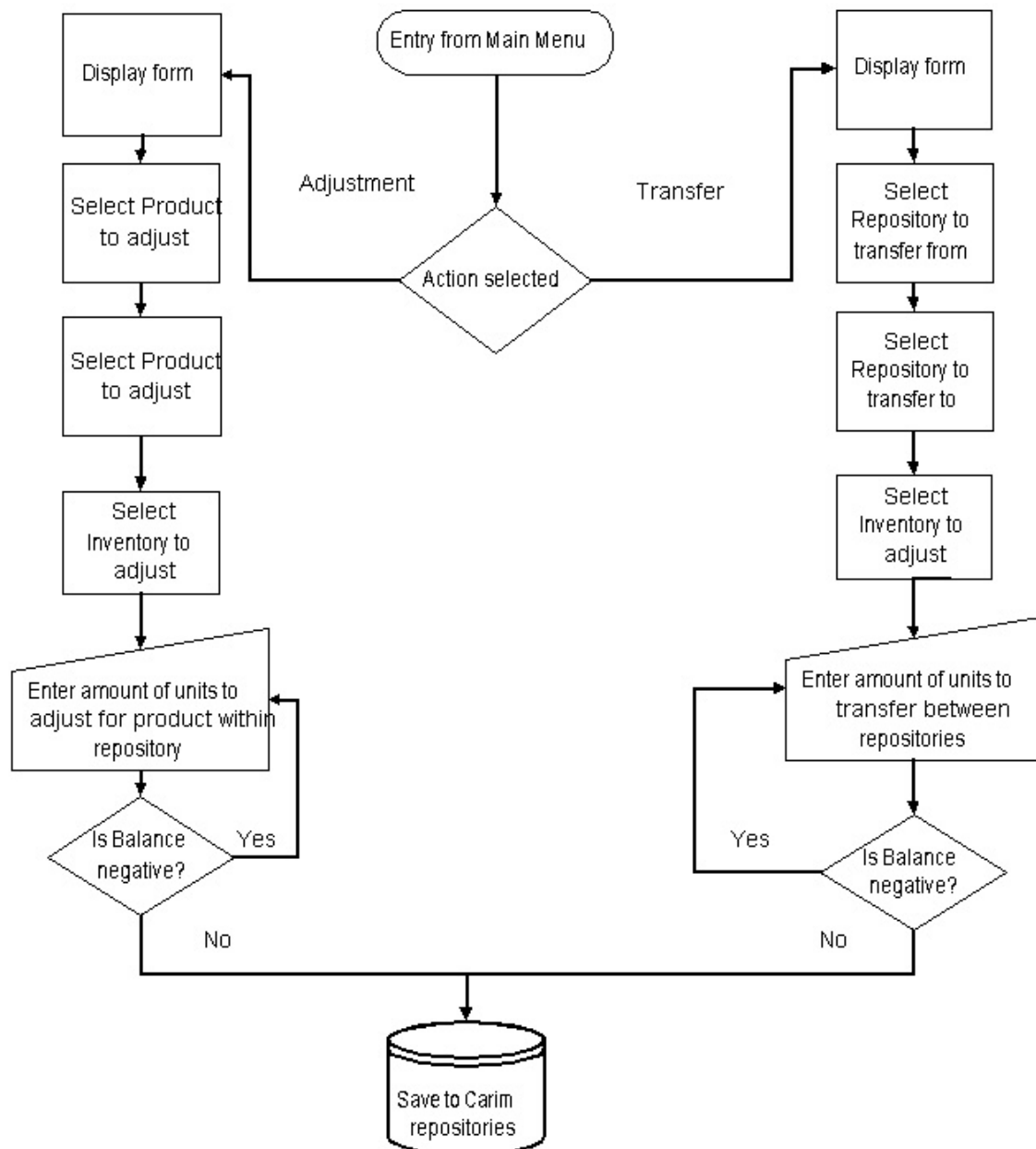
## Receiving Module



## Shipping Module



## Inventory Module





# Entry from Main Menu











## Utility Table Information Module

